Crosswalk of Changes Made to F329 Unnecessary Drugs Effective Date: 12-08-06

1. Instructors Manual - Session 3

DELETE: Power point slide 29 - Page 57

A 66 yr old woman is new to the facility and is in jeopardy of being sent back to the hospital because of behavioral problems. Her past medical history is significant for schizoaffective disorder, seizure disorder and overactive bladder. Her target behaviors are paranoia, hallucinations, lashing out at staff (physically and verbally) as well as decreased interest in activities.

ADD: New Power Point Slide 29 - Page 57

A 66 yr old woman is new to the facility and is in jeopardy of being sent back to the hospital because of behavioral problems. Her past medical history is significant for alzheimer's disease and overactive bladder. Her target behaviors are lashing out at staff (physically and verbally) as well as decreased interest in activities.

ALSO:

Participant manual Page 10

DELETE: Slide 29

ADD: New Power Point Slide 29

II. Instructors Manual Session 3

DELETE: Power point Slide 30 on Page 58

Medications

- Valproic Acid 250mg in the morning for seizure disorder
- Risperidone 0.5mg at bedtime for schizoaffective disorder
- Oxybutynin 5mg in the morning for overactive bladder

ADD - New Power Point Slide 30 on page 58:

Medications

- Valproic Acid 250mg in the morning
- Olanzapine 10 mg at bedtime
- Oxybutynin 5mg in the morning for overactive bladder

ALSO:

Participant manual Page 10

DELETE: Slide 30

ADD: New Power Point Slide 30

III. Session 3, Instructor Manual

DELETE: Instructors information on page 58:

Make sure that the following key point is brought out during the discussion:

As noted in the guidance, admission and readmission are critical times to reevaluate medications, in relation to the resident's current symptoms and overall status.

Medications may have been added during a hospitalization, for new or temporary symptoms or to manage the acute illness. Or, the resident's condition may have changed enough that medications that were previously helpful or necessary are now less relevant or even problematic. For example, depending on their previous usage, some psychopharmacologic medications may no longer be relevant to someone who has just had a new stroke. Other medications (for example, proton pump inhibitors (PPIs) may have been used for prophylaxis during hospitalization but may not need to be continued afterwards, depending on the individual's symptoms and risks.

ADD - New Language:

Make sure that the following key points are brought out during the discussion:

- The daily dosage of olanzapine is greater than the thresholds for antipsychotic medications used to manage behavioral symptoms related to dementing illness (job aid 4). The surveyor should investigate further to ascertain the rationale for the higher dose. Investigation can include a review of hospital discharge information (e.g., discharge summary), and interviews with the physician and/or pharmacist.
- Indication for the use of valproic acid: Is it for the treatment of seizures or behavior management? If for behavior management, what is an appropriate dose?

IV. Session 3, Instructor Manual

DELETE: Instructors information on page 59

- Sometimes, discharge summaries or transfer information from hospitals omit medications or give incorrect doses. For the case cited above, the resident should have been receiving valproic acid 250mg in the morning, 250mg at noon and 750mg at bedtime for a total daily dose of 1250mg a day. In addition the patient was supposed to be receiving a dose of risperidone 0.5mg in the morning and 1.5mg at bedtime.
- The surveyor could interview staff in order to identify if there was an adjustment to these medications while the resident was hospitalized, whether follow up to the doses had occurred, or whether there was an error.

While too much medication can be hazardous, too little can also cause problems. The key is whether the staff and practitioner have reviewed the situation in order to relate doses to treatment goals and identify any issues that might affect dosing. For example, is the resident getting or taking the doses already ordered, or are extended release preparations being crushed inappropriately?

ADD - New Language:

• Both olanzapine and oxybutynin are noted to have anticholinergic side effects (Job aid 7). Investigate through clinical record review and interview as to whether the additive anticholinergic effects may be impacting the resident, such as increasing behavioral symptoms.

V. Session 3 Instructors Manual

DELETE: The following Instructors information on page 79

Attempted tapering may be clinically contraindicated if:

- A resident's target symptoms return or worsen after the most recent tapering attempt, and they cannot be controlled by some other approach and they are adversely affecting the resident's comfort, health, or safety, or that of others, or
- A physician has documented the clinical rationale for why any additional attempted tapering at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

ADD: New Instructors information on page 79

Attempted tapering may be clinically contraindicated if:

- The continued use is in accordance with relevant, current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

VI. Session 7 Instructors Manual

DELETE: The following Instructors information on page 12

Observe whether medications are administered consistently over time and across various shifts, in accordance with orders.

ADD: New Instructors information on page 12

Observe whether medication related interventions are consistently implemented over time and across various shifts, in accordance with orders.

VII. Appendix B

The Instructors and Participants Manuals:

DELETE: on page 21

• The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; and

ADD: New Language:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

VIII. Appendix B

The Instructors and Participants Manuals:

DELETE: The following on Page 22

• The physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Considerations Specific to Sedatives/Hypnotics. For as long as a resident remains on a sedative/hypnotic that is used routinely during the previous quarter, the facility should attempt to taper the medication at least quarterly. Before one can conclude that tapering is clinically contraindicated for the remainder of that year, tapering must have been attempted during the previous three quarters. For the use of sedative/hypnotics, clinically contraindicated means that the physician has documented the clinical rationale for why any additional attempted tapering at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedative/Hypnotics). During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated. The tapering may be considered clinically contraindicated, if:

- The resident's target symptoms returned or worsened after the most recent attempt at a tapering within the facility; and
- The physician has documented the clinical rationale for why any additional attempted tapering at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

ADD: New Language

Attempted Tapering Relative to Continued Indication or Optimal Dose

As noted, attempted tapering is one way to determine whether a specific medication is still indicated, and whether target symptoms and risks can be managed with a lesser dose of a medication. As noted, many medications in various categories can be tapered safely. The following examples of tapering relate to two common categories of concern:

sedatives / hypnotics and psychopharmacologic medications (other than antipsychotic and sedatives/hypnotics medications).

Tapering Considerations Specific to Sedatives/Hypnotics. For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use the facility should attempt to taper the medication quarterly unless clinically contraindicated. Clinically contraindicated means:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics). During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated. The tapering may be considered clinically contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

IX. Appendix B

In the Instructors and Participants Manuals

DELETE: The following on Page 39

12) verbal expressions or behavior that are not due to the conditions listed above and do not represent a danger to the resident or others

ADD: New Language:

12) verbal expressions or behavior that are not due to the conditions listed under "Indications" and do not represent a danger to the resident or others

X. Appendix B

In the Instructors and Participants Manuals

DELETE: The following on Page 49 within the discussion of Cholinesterase Inhibitors:

Duration

• If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

ADD: No replacement language added

XI. Appendix B

In the Instructors and Participants Manuals

On page 59, we added an additional formulation of zolpidem under the Sedative/Hypnotic section $\,$

ADD: Zolpidem CR 6.25mg

XII. Job Aid 4 Dosage Tables

In the Instructors and Participants Manuals

We added an additional formulation of zolpidem under the Sedative/Hypnotic section $\,$

ADD: Zolpidem CR 6.25mg

XIII. Job Aid 4 Dosage Tables

In the Instructors and Participants Manuals

DELETE: Temazepam 7.5mg

ADD: Temazepam 15mg to be consistent with what is in Table I in the guidance.

XIV. Job Aid 6 Table 1

In both the Instructors and Participants Manuals

Delete: Language on page 14

or 12) verbal expressions or behavior that are not due to the conditions listed above and do not represent a danger to the resident or others

ADD: New Language

12) verbal expressions or behavior that are not due to the conditions listed under "Indications" and do not represent a danger to the resident or others

XV. Job Aid 6 Table 1

In both the Instructors and Participants Manuals

DELETE: For cholinesterase inhibitors, delete the following language on page 24 Duration

 If used to manage behavior, stabilize mood, or treat a psychiatric disorder, refer to Section V – Tapering of a Medication Dose/Gradual Dose Reduction (GDR) in the guidance

XVI. Job Aid 6 Table 1

In both the Instructors and Participants Manuals

On page 33, we added an additional formulation of zolpidem under the Sedative/Hypnotic section

ADD: Zolpidem CR 6.25mg

XVII. Job Aid 10 Page 1

In both the Instructors and Participants Manuals

DELETE: Language on page 1

The GDR may be considered contraindicated, if the:

- Resident's target symptoms returned or worsened after the most recent attempt at a GDR within the facility; *and*
- Physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

ADD: the following language

The GDR may be considered contraindicated, if:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at
 a GDR within the facility and the physician has documented the clinical rationale for
 why any additional attempted dose reduction at that time would be likely to impair
 the resident's function or cause psychiatric instability by exacerbating an underlying
 medical or psychiatric disorder.

XVIII. Job Aid 10

In the Instructors and Participants Manuals

DELETE: Language on page 2

under Frequency for Sedatives/Hypnotics:

If used routinely (>50%) of the time during the previous quarter, the facility should attempt to taper the medication at least quarterly.

Tapering must be attempted during the previous three quarters before it is considered clinically contraindicated for that year.

ADD: New language under Frequency for Sedatives/Hypnotics:

If used routinely during the previous quarter, the facility should attempt to taper the medication at least quarterly.

Tapering must be attempted during the previous three quarters before it is considered clinically contraindicated for that year.

For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer's recommendations for duration of use the facility should attempt to taper the medication quarterly unless clinically contraindicated

XIX. Job Aid 10

In the Instructors and Participants Manuals

DELETE: Language on page 2

Under Clinical Contraindications for Sedatives/Hypnotics:

For the use of sedative/hypnotics, clinically contraindicated means the physician has documented the clinical rationale for why any additional attempted tapering at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder

Add: language under Clinical Contraindications for Sedatives/Hypnotics

Clinically contraindicated means:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent
 attempt at tapering the dose within the facility and the physician has documented
 the clinical rationale for why any additional attempted dose reduction at that time
 would be likely to impair the resident's function or cause psychiatric instability by
 exacerbating an underlying medical or psychiatric disorder.

XX. Job Aid 10

In the Instructors and Participants Manuals

DELETE: Language on page 2

under Clinical Contraindications for: Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics)

The tapering may be considered clinically contraindicated, if the:

- Resident's target symptoms returned or worsened after the most recent attempt at a tapering within the facility; <u>and</u>
- Physician has documented the clinical rationale for why any additional attempted tapering at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.

ADD: language on page 2 under Clinical Contraindications for Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics):

Clinically contraindicated means:

- The continued use is in accordance with relevant current standards of practice and the physician has documented the clinical rationale for why any attempted dose reduction would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder; or
- The resident's target symptoms returned or worsened after the most recent attempt at tapering the dose within the facility and the physician has documented the clinical rationale for why any additional attempted dose reduction at that time would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder.